

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE	9000.9	6/10/19
-----------------------	--------	---------

INSPECTION OF CLOSED-FACE SANDWICHES FOR EXPORT TO CANADA

I. PURPOSE

A. This directive provides instructions to inspection program personnel (IPP) regarding verifying compliance with Hazard Analysis and Critical Control Points (HACCP) systems, Sanitation Standard Operating Procedures (Sanitation SOPs) and [9 CFR 430](#) (Requirements for Specific Classes of Product) in establishments that produce closed-face sandwiches (including non-traditional closed-face sandwiches, e.g., breakfast sandwiches) for export to Canada. This directive also includes instructions to IPP on how to notify Agricultural Marketing Service (AMS) of a sample that cannot be collected and new instructions on how IPP are to handle a request to add new products for an existing establishment. These instructions were previously in an FSIS notice.

B. IPP are to be aware that all meat or poultry closed-faced sandwiches (including sandwiches made with pancakes or waffles) are not ordinarily under FSIS jurisdiction, they are under Food and Drug Administration (FDA) jurisdiction.

II. BACKGROUND

A. Closed-face sandwiches, i.e., ready-to-serve, hand-held products consisting of a meat or poultry filling between two slices of bread, a biscuit, or a bun, are not under FSIS jurisdiction and are under FDA jurisdiction. Similarly, meat or poultry sandwiches made with pancakes or waffles instead of slices of bread are under FDA jurisdiction.

B. In February 2013, the Canadian Food Inspection Agency (CFIA) audited the United States' food safety inspection system for meat and poultry products intended for export to Canada. CFIA's final audit report found that HACCP plans and *Listeria monocytogenes* (*Lm*) controls for ready-to-eat (RTE) meat and poultry products were not required when establishments prepared products not under FSIS jurisdiction (such as closed-face sandwiches) under FSIS's voluntary reimbursable inspection service. CFIA notified FSIS that CFIA requires that these products be produced under HACCP plans and *Lm* control programs consistent with [9 CFR 430](#). To address Canada's requirements, FSIS announced the establishment of an AMS RTE Canada Export Verification (EV) Program in the [Federal Register notice, "Export Verification Program: Microbiological Testing of Ready-To-Eat Products Destined for Canada."](#) This EV program includes both verification of HACCP and *Lm* control programs as well as AMS product testing for *Salmonella* and *Lm* in RTE closed-face sandwiches.

DISTRIBUTION: Electronic

OPI: OPPD

III. DO PROCEDURES FOR ADDING ESTABLISHMENTS TO THE AMS RTE CANADA EV PROGRAM

A. When a facility submits FSIS Form 5200-6, *Application/Approval for Voluntary Reimbursable Inspection Service* and expresses interest in producing RTE closed-face sandwiches for export to Canada by stating this on company letterhead and checking block 14 of the 5200-6, the DO is first to follow the instructions in [FSIS Directive 5220.1](#), *Granting or Refusing Inspection; Voluntary Suspending or Withdrawing Inspection; and Reinstating Inspection Under PHIS*, for approving voluntary inspection service.

B. Because of Canada's requirements for this type of product, the general requirements for voluntary inspection of RTE closed-face sandwiches intended for export to Canada include producing the product under a HACCP plan, Sanitation Standard Operating Procedures (SOPs), and a *Lm* control program as part of the AMS RTE Canada EV Program.

C. IPP are to be aware that the applicable regulatory requirements for this voluntary inspection service are found in [9 CFR 417](#), [9 CFR 416](#), [9 CFR 430](#), [9 CFR 350.3\(b\)](#), [9 CFR 350.3\(c\)](#), [9 CFR 362.2\(a\)](#), [9 CFR 312.2\(b\)\(2\)](#), and [9 CFR 381.96](#).

D. Once the facility has been approved for the voluntary inspection service under the AMS RTE Canada EV program, DO personnel, with the grant curator role in the Public Health Information System (PHIS) are to:

1. Check the "AMS RTE Canada EV Program" as well as "Food Inspection" in the Application for Voluntary Services on the Grants and Approvals page in the establishment profile; and
2. E-mail AMS at NationalScienceLaboratories@ams.usda.gov indicating that establishment V-##### has joined the AMS RTE Canada EV Program. The e-mail is to include the following:
 - a. Company name;
 - b. Establishment number;
 - c. Contact person name; and
 - d. Contact person phone number.

IV. IPP PROCEDURES FOR VERIFYING COMPLIANCE FOR CLOSED-FACE SANDWICHES UNDER THE AMS RTE CANADA EV PROGRAM

A. In establishments that produce RTE closed-face sandwiches for export to Canada under the [AMS RTE Canada EV Program](#), FSIS personnel are to perform HACCP, Sanitation SOP, and label verification tasks assigned by PHIS as described in [FSIS Directive 12,600.1](#), *Voluntary Reimbursable Inspection Services* and [FSIS Directive 5000.1](#), *Verifying an Establishment's Food Safety System*. IPP are to perform these tasks only when RTE closed-face sandwiches are being produced for export to Canada.

B. In general, IPP are to ensure that when they perform the applicable inspection tasks, they verify the regulatory requirements for lots of product that are eligible for export to Canada. IPP are not to perform these verification tasks on RTE closed-face sandwiches that are intended only for domestic commerce.

C. IPP are to perform the HACCP and Sanitation SOP inspection tasks at the frequency they are assigned in PHIS if the establishment typically produces RTE closed-face sandwiches for export to

Canada every day or on most operating days (e.g., four or more days per week). IPP are to perform the tasks less frequently if the establishment typically produces RTE closed-face sandwiches for export to Canada intermittently or infrequently (e.g., typically three or fewer days per week). IPP are to mark tasks “Not Performed” with the justification “Product/Process Not Available” when eligible products are not available, keeping in mind that in some cases it is appropriate to perform the tasks using records of a previous day’s production rather than marking a task as “Not Performed.” IPP are to refer to the table below regarding how often to perform the tasks.

Inspection Task Name	If the establishment typically produces RTE closed-face sandwiches for export to Canada every day or most operating days:	If the establishment typically produces RTE closed-face sandwiches for export to Canada only intermittently or infrequently:
AMS - Pre-Op Sanitation SOP Review and Observation (V) or AMS - Pre-Op SSOP Record Review (V)	Once per week (on a day when the establishment is producing product eligible for export to Canada – Record Review can be performed based on a previous day’s production)	Once per week (on a day when the establishment is producing product eligible for export to Canada – Record Review can be performed based on a previous day’s production)
AMS – Operational Sanitation SOP Review and Observation (V) or AMS – Operational Sanitation SOP Record Review (V)	Daily (either Review and Observation or Record Review each day when the establishment is producing product eligible for export to Canada – Record Review can be performed based on a previous day’s production)	Every day the establishment is producing eligible product (either Review and Observation or Record Review each day when the establishment is producing product eligible for export to Canada - Record Review can be performed based on a previous day’s production)
AMS - Fully Cooked-Not Shelf Stable HACCP (V)	Twice per week (may sometimes be performed based on records of a previous day’s production)	Every day the establishment is producing eligible product (may sometimes be performed based on records of a previous day’s production)

D. When the sampling task AMS_PROD_RTE appears in PHIS, IPP are to:

NOTE: This program is separate from other FSIS *Lm* sampling programs. If both an AMS_PROD_RTE and RTEPROD are scheduled for the same month, both are to be collected.

1. Collect the samples from product produced under this program as described in Chapter 4, Section II of [FSIS Directive 10,240.4, Verification Activities for the *Listeria monocytogenes* \(Lm\) Regulation and the Ready-to-Eat \(RTE\) Sampling Program](#). If the FSIS inspector is unable to collect the samples, the inspector is to enter the reason and/or justification into PHIS and send the reason they were unable to collect sample to AMS NSL via e-mail at NationalScienceLaboratories@ams.usda.gov;
2. Submit the samples as described in the instructions accompanying the sampling supplies. These samples and supplies are handled by the AMS National Science Laboratories in Gastonia, NC. If IPP have questions about the sample supplies, they are to contact NationalScienceLaboratories@ams.usda.gov;

3. If the shipping company does not already have a regularly scheduled pick-up, request that the establishment call for a pick-up the same day;
4. Inform the establishment that the product is not eligible to bear the mark of inspection or be certified for export unless acceptable sample results are obtained; and
5. Obtain sampling results in the Laboratory Information Management System (LIMS). If the sample is negative, the product is then eligible to receive export certification. If the sample is positive, IPP are to refuse to certify the product represented by the sample for export, notify the establishment, and document the notification on a Memorandum of Interview (MOI). IPP are to immediately notify their Frontline Supervisor (FLS) of positive results, and DO management is to notify its associated FDA District Office (DO) of the result as per the FDA/USDA/FSIS Memoranda of Understanding (MOU) for Dual Jurisdiction Firms.

D. When IPP receive an e-mail request from AMS to verify new products being added to the list of eligible products for an establishment, IPP are to:

1. Verify that the product is covered under a Sanitation SOP and HACCP plan; and
2. Reply all to the e-mail indicating whether or not the products are covered by a Sanitation SOP and HACCP plan.

E. If IPP find that an establishment has not followed the provisions of [9 CFR 416](#), [417](#), or [430](#), they are to refuse to certify the product intended for export to Canada. IPP are to document their findings on a MOI in the PHIS task that relates to the deviation from a country requirement. If IPP find repeated deviations from country requirements, they are to contact their supervisor who will determine if further action is needed. If the DO has concerns that an eligible establishment needs to be removed from this voluntary inspection program due to repeated deviations from country requirements, the DO is to contact importexport@fsis.usda.gov. Once contacted by the DO, the Office of Policy and Program Development (OPPD) is to notify other agencies as necessary.

V. QUESTIONS

A. Refer technical questions about non-traditional closed-face sandwiches produced for domestic commerce to the OPPD Labeling and Program Delivery Staff through [askFSIS](#) or by telephone at 1-301-504-0878. When submitting a question, use the **Submit a Question** tab and enter the following information in the fields provided:

- Subject Field: Enter **9000.9**.
- Question Field: Enter question with as much detail as possible.
- Product Field: Select **Labeling** the drop-down menu.
- Category Field: Select **Labeling Regulations, Policies and Claims** from the drop-down menu.
- Policy Arena: Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press **Continue** and at the next screen press **Finish Submitting Question**.

B. Refer technical questions about the AMS RTE Canada EV Program to the OPPD Import/Export Policy Development Staff through [askFSIS](#) or by telephone at 1-855-444-9904. When submitting a question, use the **Submit a Question** tab and enter the following information in the fields provided:

Subject Field: Enter **9000.9**.

Question Field: Enter question with as much detail as possible.

Product Field: Select **Export** the drop-down menu.

Category Field: Select **Export Certificates** from the drop-down menu.

Policy Arena: Select **International Import/Export** from the drop-down menu.

When all fields are complete, press **Continue** and at the next screen press **Finish Submitting Question**.

NOTE: Refer to [FSIS Directive 5620.1](#), *Using askFSIS*, for additional information on submitting questions.

A handwritten signature in black ink that reads "Sabrina J. Wagner". The signature is written in a cursive style with a large initial 'S'.

Assistant Administrator
Office of Policy and Program Development